

# Fiedler Encyclopedia of Excipients

## Vol. 2 L-Z

Encyclopedia Part: Pages 841 - 1554

Directory of Manufacturers: Pages 1555 - 1609

## Der Pharmazeutische Betrieb · Vol. 9

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## Steareth-16

**Definition** INCI name for ▶polyethylene glycol(16)stearyl ether.

## Steareth-20

**Definition** INCI name for ▶polyethylene glycol(20)stearyl ether.

## Steareth-21

**Definition** INCI name for ▶polyethylene glycol(21)stearyl ether.

## Steareth-25

**Definition** INCI name for ▶polyethylene glycol(25)stearyl ether.

## Stearic acid

(Cognis, Merck, OLEON, PG Chemicals, Protameen)

**Definition** Acidum stearicum, octadecanoic acid, CAS 57-11-4,  $\text{CH}_3(\text{CH}_2)_{16}\text{COOH}$ , mol wt 284.49. — ▶Emersol, Neofat 18.

**Properties** White leaflets or white powder, with fat-like odor, insoluble in water, soluble in alcohols and fat solvents. S. can crystallize from solution in three different forms: A, B, and C. According to W. Beckmann determination of the exact solubility of S. in decane, methyl alcohol and butanone allows statements concerning the stability ranges of the three modifications (Fette, Seifen, Anstrichmittel **86**, 217 [1984]). The crystal structure of S. can be affected by emulsifiers (N. Garti et al., J. Amer. Oil Chemists' Soc. **58**, 1058 [1981]; C. A. **96**, 50953 [1982]). According to P. D. Cratin the surface and interfacial properties of S. are markedly pH dependent (J. Dispers. Sci. Technol. **14**, 559 [1993]; Internat. Pharm. Abstr. **31**, No. 3-1458 [1994]). A study of the effects of S. and ▶sterculic acid on morphology of cultured rat hepatome cells (X. Huang et al., Disi Junyi Daxue Xuebao **17**, 321 [1996]), C. A. **126**, 69815 [1997]). In in vitro experiments N. A. Habib et al. observed some antitumorigenic action of S. (Brit. J. Cancer **56**, 455 [1987]; C. A. **108**, 31457 [1988]). In an overview (64 references) D. L. J. Opydyke reports on the biological data of the S. (Food, Cosmet. Toxicol. **17**, 383 [1979]). According to H. Thaler and H.-J. Kleinau (Fette, Seifen, Anstrichmittel **71**, 92, 261 [1969]) saturated fatty acids, e. g. S. and their methyl esters, tend to autoxidation. On the quality requirements of the Toilet Goods Association for S. see Soap, Perf. Cosmet. **27**, 744 (1954).

**Product data** Mp 69.6°, bp<sub>100</sub> 298°, d<sub>20</sub> 0.9408, n<sub>D</sub><sup>80.2</sup> 1.4299. Merck provide S. which conforms to the requirements of the following pharmacopoeias: FU, NF, Ph Helv and Ph Nord.

**Applications** In drug production, for coating of bitter drug substances; the addition of S. prevents the change in color of ascorbic acid tablets (Austral. P. 239 831 of 10. 3. 59/26. 7. 62; C. A. **63**, 1670 [1967]), together with its sodium salt, as an anionic emulsifier for creams (stearate creams). A mixture of 18.9 (g) polyethylene glycol, 12.6 water, 36 diethylene glycol, 5 citric acid, 2.5 EDTA (Trilon B), 15 o-tolylbiguanide, 5 tartaric acid and 5 benzyl alcohol is a good stabilizer for cosmetic S. (A. A. Zelenetskaya et al., Russ. P. 278 038 of 15. 5. 69/ 5. 8. 70; C. A. **74**, 34560 [1971]).

**Toxicology** LD<sub>50</sub> (rat, i. v.) 22 mg/kg, (mouse, i. v.) 23 mg/kg; cat (i. v.), lethal dose 5 mg/kg. An overview reveals that S. is only slightly toxic (tested on fish) and irritates skin and mucosa. An irritant effect was also found after inhalation of S. (Dang. Proper Ind. Mater. Rep. **9**, 73 [1989]; Toxicol. Abstr. **12**, No. 11-7695 [1989]). A. C. de Groot et al. observed a case of contact allergy to S. and one to glycerol stearate (Contact Dermatitis **19**, 76 and 77 [1988]).

The CIR Expert Panel of the CTFA prepared the final report for S. and concluded, that S., in concentrations used in cosmetics, can be declared as safe (J. Amer. Coll. Toxicol. **6**, 321 [1987]; C. A. **108**, 1010192 [1988]).

## Stearic acid, almost germ-free

**Definition** ▶Emersol 132 (USP grade) and Emersol TP (Food grade) undergo microbiological tests after production. In accordance with a certificate they contain < 50, usually < 10 micro-organisms/g. This applies to bacteria and fungi (Soap Cosmet. Chem. Specialties **48**, No. 3, 111 [1972]).

## Stearic acid butyl ester

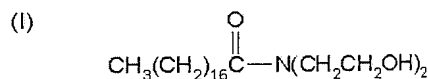
**Definition** Butyl stearate, CAS 123-95-5,  $\text{CH}_3 \cdot (\text{CH}_2)_{16} \cdot \text{COO}(\text{CH}_2)_3 \cdot \text{CH}_3$ , C<sub>22</sub>H<sub>44</sub>O<sub>2</sub>, mol wt 340.

**Product data** D<sub>20</sub> 0.859, mp 20°.

**Applications** Plasticizer.

## Stearic acid diethanolamide

**Definition** Stearoyl diethanolamide, N,N-bis(2-hydroxyethyl)stearamide, INCI Stearamide DEA, RD 977058-29-9, CAS 93-82-3, C<sub>22</sub>H<sub>45</sub>NO<sub>3</sub>, a mixture of the diethanolamides of stearic acid (I).



## Stearic acid ester of dextran

**Definition** ▶Dextran.

## Stearic acid ethyl ester

**Definition** INCI Ethyl Stearate, CAS 111-61-5, C<sub>20</sub>H<sub>40</sub>O<sub>2</sub>.

## Stearic acid hydrazide

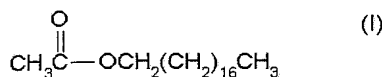
**Definition** RD 977058-34-6, CAS 4130-54-5, C<sub>18</sub>H<sub>35</sub>N<sub>2</sub>O, C<sub>17</sub>H<sub>35</sub>CO-NH-NH<sub>2</sub>

**Properties** A non hygroscopic, fine, white powder, insoluble in water and ethyl alcohol, sparingly soluble in hydrocarbons and fats, soluble in hot benzene and in mixtures of toluene and isopropyl or butyl alcohol, contains min. 95 % mono-S., max. 5 % di-S. and max. 0.03 % free hydrazine.

**Applications** S. is recommended as a stabilizer for toilet soaps (0.025–0.05 %), it is compatible with the usual antimicrobially effective substances and does not impair their spectrum.

**Toxicology** LD<sub>50</sub> (rat, oral) 5 g/kg; good skin and mucosal tolerance; is not absorbed by rabbit skin.



**Stearyl alcohol**

(Aceto, Cognis, Goldschmidt, Protameen)

**Definition** Octadecanol, octadecyl alcohol, stearin alcohol, CAS 112-92-5,  $\text{CH}_3(\text{CH}_2)_{16}\text{CH}_2\text{OH}$ ,  $\text{C}_{18}\text{H}_{38}\text{O}$ , mol wt 270.48. — ▶Fatty alcohols, ▶Lorol, ▶Stearylaz 18, ▶Exxal 18, ▶Lanette 18, ▶Tego Alkanols.

**Properties** Colorless leaflets, insoluble in water, soluble in alcohol and fat solvents. Mp 59°, d 0.8124, bp 210.5°.

**Applications** S. is added to ointments as a solidifying agent, to creams as an emulsion stabilizer. Paraffin oil-water emulsions, containing alkyl sulfates, can be further stabilized by addition of S. (G. W. Hallworth, J. Pharm. Sci. 25, Suppl. 87 P [1973]; Cosmet. Perfum. 89, No. 11, 76 [1974]). According to G. E. Mapstone (Cosmet. Perfum. 89, No. 11, 31 [1974]) the incorporation of pure S. or cetyl alcohol into emulsions may yield unstable products, since crystallization, possibly arising during production, removes the alcohol(s) from the interphase. Such changes can largely be prevented by addition or increase of the content of a co-emulsifier.

**Toxicology** The CIR Panel has reviewed the findings presented concerning the toxicity of S. and concluded, that S. can be declared as safe in concentrations used in cosmetic agents (R. L. Elder, J. Amer. Coll. Toxicol. 4, No. 5, 1 [1985]; Toxicol. Abstr. 9, No. 4-2327 [1986]; C. A. 104, 74764 [1986]).

**References** Stearyl alcohol and its Derivatives. Spec. Chem. 6, No. 1, 17 (1986).

**Stearyl alcohol, ethoxylated**

**Definition** Ethoxylated S. was synthesized and isolated; properties and product data (J. Scotney and E. V. Truter, J. Soc. Cosmet. Chemists 22, 201 [1971]). Impact of S. on the foaming characteristics of shampoos (S. A. De Ragon et al., J. Soc. Cosmet. Chemists 20, 777 [1969]). — ▶Fatty alcohols (ethoxylated) and Polawax.

**Stearyl amide ether carboxylic acid**

**Definition** ▶Akypo AH 400.

**Stearylamidopropyl morpholine lactate**

**Definition** ▶Isostearylamidopropyl morpholine lactate.

**Stearyl amine**

**Definition** Octadecyl amine, stearamine, CAS 124-30-1, an aliphatic amine derived from stearic acid,  $\text{CH}_3(\text{CH}_2)_{16}\text{CH}_2\text{NH}_2$ ,  $\text{C}_{18}\text{H}_{39}\text{N}$ .

**Toxicology** The CIR Expert Panel of CTFA has published the Final Report for S. and concluded, that the available data are not sufficient (J. Amer. Coll. Toxicol. 14, 730 [1995]; Toxicol. Abstr. 19, No. 7-4970 [1996]).

**Stearylaz 18**

**Definition** (Tensachem). Trade name for ▶stearyl alcohol.

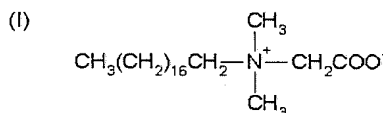
**Stearyl Benzoate**

(Finetex)

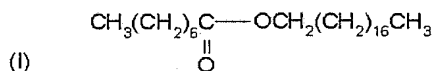
**Definition** INCI name for stearyl benzoate. ▶Finsolv Grades (F. 116).

**Stearyl betaine**

**Definition** Stearyl dimethyl glycine, RD 977067-64-3, CAS 820-66-6,  $\text{C}_{22}\text{H}_{45}\text{NO}_2$ , (I).

**Stearyl caprylate**

**Definition** RD 977063-11-8, CAS 18312-31-7,  $\text{C}_{26}\text{H}_{52}\text{O}_2$ , (I).

**Stearyl citrate**

**Definition** Produced by esterification of citric acid with stearyl alcohol (mixture of citric acid mono-, di- and tri-esters), CAS 1337-33-3,  $\text{C}_{24}\text{H}_{44}\text{O}_7$ .

**Properties** Insoluble in water, soluble in hot ethyl alcohol.

**Applications** Used as an emulsifier in the food industry.

**Stearyl dihydroxyethyl glycine**

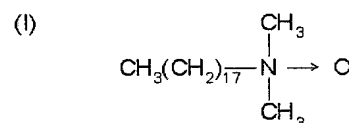
**Definition** ▶N-(Carboxymethyl)-N,N-bis(2-hydroxyethyl)-1-octadecaneaminium hydroxide, inner salt.

**Stearyl Dimethicone**

**Definition** INCI name for a polysiloxan/polyalkylene copolymer, trade name ▶Abil Wax 9800.

**Stearyl dimethyl amine oxide**

**Definition** Stearamine Oxide, CAS 2571-88-2,  $\text{C}_{20}\text{H}_{43}\text{NO}$ , mol wt 313, abbreviation: SDMAO, an aliphatic amine oxide derived from stearic acid (I). — ▶Ammonyx SO.



**Product data** Active substance 23.4 %, water 76.6 %,  $d_{40}^{25}$  0.947 g/cm<sup>3</sup>, viscosity of a 10 % aqueous solution (60°) 248 mPa·s, yield point 50°.

HLB (calculated) 8.3–8.8, measured 5.5–6 (K. R. Smith et al., J. Soc. Cosmet. Chemists 38, 43 [1987]).

**Toxicology** The CIR Expert Panel of the CTFA prepared the final report for S. and concluded that S. may be used in leave-on cosmetic preparations, up to a concentration of 5.1 % (FDC Reports [Rose Sheet] 13, No. 36, 7 [Sept. 7, 1992]).